

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF MISSISSIPPI  
OXFORD DIVISION**

**ROY WILMOTH, JR.**

**PLAINTIFF**

**v.**

**CIVIL ACTION NO. 3:20-CV-120-NBB-RP**

**ALEX M. AZAR, II, in his official  
capacity as Secretary of the U.S.  
Department of Health and Human Services**

**DEFENDANT**

**MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**

Roy Wilmoth, Jr. is a Medicare beneficiary who is challenging a decision of the Medicare Appeals Council denying coverage for the rental of a medical device in 2018 and finding the non-party supplier, Novocure, Inc., financially responsible for the non-covered costs. Mr. Wilmoth does not allege that he has suffered any injury, nor can he. Thus, Wilmoth lacks Article III standing to bring this action because he has suffered no injury-in-fact. This action should be dismissed because there is no Article III case or controversy.

**Statutory and Regulatory Framework**

Medicare is a federal health insurance program for the elderly and/or disabled. 42 U.S.C. § 1395. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id.* Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, “no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services [] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . .” 42 U.S.C. § 1395y(a)(1)(A).

In order for a beneficiary to challenge a denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare Administrative Contractor, and if the claim is denied, the beneficiary must generally exhaust the following

four levels of administrative review before filing suit in district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904(a)(2). First, the dissatisfied beneficiary may seek a redetermination from the Medicare Administrative Contractor, which must be performed by a person who did make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor (QIC) whose panel members must have “sufficient medical, legal, and other expertise, including knowledge of the Medicare program.” 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.904(a)(2), 405.968(c)(1).

At the third level, a dissatisfied beneficiary can request a hearing before an administrative law judge (ALJ), who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.904(a)(2), 405.1000-02, 405.1046.

Finally, a beneficiary dissatisfied with the ALJ’s decision may request review of the ALJ’s decision by the Medicare Appeals Council (the MAC), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.904(a)(2), 405.1100, 405.1122. The Council’s decision (or the ALJ decision, if not reviewed by the MAC) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. A dissatisfied claimant is entitled to judicial review of the Secretary’s decision in the district court “as is provided in [42 U.S.C.] 405(g).” 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary’s findings of fact “if supported by substantial evidence, shall be conclusive.” 42 U.S.C. § 405(g).

### **Factual and Procedural Background**

After being severed and transferred from the District Court of the District of Columbia, Plaintiff filed an Amended Complaint in this Court on May 21, 2020. Docket 33.

In relevant part, Mr. Wilmoth alleges in his Amended Complaint that he was diagnosed with glioblastoma in February 2016 for which he was prescribed tumor treatment field therapy (TTFT), a treatment delivered through the rental of equipment known as the Optune system from Novocure, Inc. Docket 33, pp. 4-5. He alleges he submitted a claim for payment for the TTFT treatment that has been subject to administrative review under the Medicare statute. *Id.* at pp. 6-9.

More specifically, Mr. Wilmoth alleges that after a series of ALJ decisions that found the Optune system a covered treatment under Medicare, an ALJ issued a decision on May 7, 2019, holding the TTFT treatment “not medically reasonable or necessary” and was therefore not a covered Medicare benefit. *Id.*

Mr. Wilmoth appealed to the MAC, noting the prior favorable decisions and arguing that the Secretary was collaterally estopped from re-litigation the coverage issue. *Id.* at 9. On October 15, 2019, the MAC issued a decision agreeing with the ALJ and adopting the ALJ’s decision. Docket 41-1, pp. 1-8. The MAC also held the *supplier* [Novocure] financially responsible for the non-covered costs. *Id.* at 8. The MAC did not hold Mr. Wilmoth financially responsible for any non-covered costs. *Id.*

Mr. Wilmoth filed Plaintiff filed the instant action under 42 U.S.C § 405(g), seeking judicial review of the MAC’s October 15, 2019 decision. Docket 33.

### **Standard of Review**

#### **Fed. R. Civ. P. 12(b)(1)**

As courts of limited jurisdiction, federal courts acquire jurisdiction only by statute or through the United States Constitution. *In re FEMA Trailer*, 668 F.3d at 286; *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). The court must dismiss a case when the plaintiff fails to establish subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). A

case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case. *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5<sup>th</sup> Cir. 1998).

The burden of establishing federal jurisdiction rests on the party seeking the federal forum. *Stockman v. Fed. Election Comm'n*, 138 F.3d 144, 151 (5<sup>th</sup> Cir. 1998). A district court may determine its jurisdiction based on: “the complaint alone; (2) the complaint supplemented by undisputed facts evidence in the record; or (3) the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.” *Ramming v. United States*, 281 F.3d 158, 162 (5<sup>th</sup> Cir. 2001).

#### **Fed. R. Civ. P. 12(b)(6)**

Dismissal under Rule 12(b)(6) is appropriate where a complaint fails “to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). A complaint meets this standard only if it “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While a complaint’s allegations generally need not be detailed, the must “possess enough heft” to propel the claims across a threshold of plausibility. *Twombly*, 550 U.S. at 557. Under this standard, the court must accept all allegations of material fact as true and must construe them in the light most favorable to the plaintiff. *Hospital Bldg. Co. v. Trustee of Rex Hospital*, 425 U.S. 738, 740 (1976). All ambiguities or doubts must be resolved in the plaintiff’s favor. *Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969). However, conclusions of law, conclusory allegations, unreasonable inferences, or unwarranted deductions of fact need not be accepted as true. *Harold H.*

*Huggins Realty, Inc. v. FNC, Inc.*, 634 F.3d 787, 796 (5<sup>th</sup> Cir. 2011). Courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

### **Argument**

This Court lacks jurisdiction to grant Mr. Wilmoth any relief because he has no legal obligation to pay the subject medical charges and therefore has not suffered any concrete injury sufficient to confer Article III standing.

Mr. Wilmoth lacks Article III standing because he has not asserted an injury in fact that is “fairly traceable” to the challenged conduct of Defendant. Under Article III, § 2 of the U.S. Constitution, federal courts can only hear live “cases” or “controversies.” The “irreducible constitutional minimum” of standing consists of three elements: the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.

*Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

Here, Mr. Wilmoth lacks an actionable injury. Again, he has only appealed the MAC’s unfavorable decision, which addressed TTFT claims for the April 19, 2018 through June 19, 2018 term. Docket 33, p. 9. However, Mr. Wilmoth notably does not allege that the Council’s unfavorable decision actually resulted in him becoming financially responsible for his TTFT claims for the April 19, 2018 through June 19, 2018 time period, nor could he, as MAC specifically found that only Novocure, Inc. – *not* Mr. Wilmoth – is responsible for the charges. Docket 41-1, pp. 7-8. Mr. Wilmoth alleges that his other claims for TTFT have been paid. Docket 33, pp. 6-9.

Mr. Wilmoth does not allege any harm except for the charges for the April 19, 2018 through June 19, 2018 term. Mr. Wilmoth alleges that his subsequent claims for TTFT have been granted. Docket 33, p. 7-8. He identifies four ALJ decisions involving dates of service post-dating the dates of service for this appeal. Docket 33, pp.7-8. Those decisions were favorable to Mr. Wilmoth and are now final regardless of the results in this litigation. This further illustrates how Mr. Wilmoth has not suffered any actual or imminent injury that could confer standing.

Further, Mr. Wilmoth has not alleged any hindrance to Novocure, Inc.'s ability to protect its own interests. *See Kowalski v. Tesmer*, 543 U.S. 125, 129-30 (2004) (to assert third-party standing, the litigant must show both a "close" relationship to the possessor of the right, and a "hindrance" to the possessor's ability to protect his own interests").

In sum, because Mr. Wilmoth has not suffered an actual or imminent injury, there is no live "case" or "controversy" and he therefore lacks standing to pursue his claim.

### **Conclusion**

This action should be dismissed in its entirety. Mr. Wilmoth lacks Article III standing to pursue his claim because he has suffered no actual or imminent injury.

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